Remarks

Claims 1-5 are presently being examined. Claims 6-60 have been withdrawn by the Examiner as being drawn to non-elected inventions.

35 U.S.C. §103(a)

Claims 1-5 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over MacLean et al. and Lund et al. Applicant respectfully disagree because the combination of MacLean et al. and Lund et al. does not teach or suggest to one skilled in the art the claimed invention, which relates to methods of treating male andropause using a combination of an estrogen agonist/antagonist and testosterone. Nor does the combination of MacLean et al. and Lund et al provide a reasonable expectation of success that a combination of an estrogen agonist/antagonist and testosterone could be used to treat male andropause.

The combination of MacLean et al. and Lund et al. is deficient because nowhere in MacLean et al. is the treatment of male andropause even mentioned. Instead, MacLean et al. recites treatment of testosterone deficiency, which is different from andropause. Adropause in men, like menopause in women, occurs later in life, and has a number of biological consequences. Moreover, nowhere in MacLean et al. is there any suggestion to combine an estrogen agonist/antagonist with testosterone. Furtherore, MacLean et al. discuss at column 13, lines 19-22, that testosterone in men is aromatized in fat, which leads to increased estrogen and that the increase in estrogen can result in negative feedback that reduces the total testosterone levels.

The Lund et al. article does not supply the elements of the claimed invention that are missing from MacLean et al. The Lund et al. article does not even mention the use of a SERM to treat andropause. Lund et al. discusses the use of testosterone alone as a possible treatment of andropause. Applicants note that even the use of testosterone as testosterone replacement therapy (TRT) for andropause is specualtive, as is shown by the last two sentences of the article on page 995.

> Because of insufficient evidence, particularly regarding psychologic safety and efficacy, general TRT in elderly hypogonadal men is not warranted. However, further clinical evaluation of TRT in men with low testosterone levels and symptoms of andropause is warranted.

Thus, the conclusion of the Lund et al. article is simply an invitation to experiment.

Lund et al. also discuss that "increasing concentrations of testosterone inhibits further secretion of GnRH through a negative feedback mechanism (See

page 952, first full paragraph). Thus, administration of exogenous testosterone can negatively impact the production of endogenous testosterone. Because of the complex negative feedback mechanisms relating to the endogenous production of testosterone as recognized in both MacLean et al. and Lund et al., it is not obvious to one skilled in the art that andropause could be treated using a combination of an estrogen agonist/antagonist and testosterone. In other words, the combination of MacLean et al. and Lund et al. do not provide a reasonable expectation of success to one skilled in the art.

Because the combination of MacLean et al. and Lund et al. do not teach or suggest the treatment of andorpause using a combination of an estrogen agonist/antagonist and testoterone, nor do they provide one skilled in the art with a reasonable expectation of success in view of the complex negative feedback mechanisms involving estrogen and testosterone, the presently claimed invention is patentable over MacLean et al. and Lund et al., and applicants respectfully request withdrawal of this rejection.

Applicants believe that in view of the remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 1-5 is respectfully requested.

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By: Todd M. Crissey

Todd M. Crissey
Registration No. 37,807
Pfizer Inc
Legal Division
Patent Department
MS: 8260-1611
Eastern Point Road
Groton, CT 06340
Phone: (860) 715-4331
Fax: (860) 441-5221